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24

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EXAMINER SOLOLA, TAOFIQ A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/799,256

**Applicant(s)**

HAAF ET AL.

**Examiner**

Taofiq A. Solola

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 21 April 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-11 is/are pending in the application.  
4a) Of the above claim(s) 5-11 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☐ Claim(s) 1-4 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☒ Certified copies of the priority documents have been received in Application No. 08/948,557.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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Art Unit: 1626

Claims 1-11 are pending in this application.

Claims 5 -11 are drawn to non-elected inventions.

***Restriction Requirement***

The election of group I, claims 1-4, with traverse in Paper filed 4/21/05 is hereby acknowledged. The traversal is on the basis that groups I to VI are related and therefore, it should not be undue burden on the Examiner to search all the groups. This is not persuasive because the groups are in fact not related for reasons set forth in the Restriction Requirement mailed 10/19/04, and therefore would be undue burden for the Examiner to search them. Applicant further argues that the requirement is an undue burden on the Applicant and the public. This is not persuasive because it is not a valid basis for Restriction Requirement. Applicant also contends that the public would be inconvenience for not knowing if applicant would file a division. This is not persuasive because it is not a valid basis for Restriction Requirement. As in the parent case, (08/948,557), applicant may elect to PGPub the instant application.

The requirement is till deemed proper and therefore made FINAL.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to

Art Unit: 1626

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, formula (I),  $R^1$  and  $R^2$  are defined as organic radicals. This implies formula (I) embraces any and all compounds, known and yet to be discovered, having the acylsulfonamide of formula (1) with any two substituents. Applicant may not claim a process of making any compound having the acylsulfonamide of formula (1) with any two substituents. Applicant must define  $R^1$  and  $R^2$  so as to ascertain what applicant is claiming. Such definition must be supported by the specification. Under US patent practice, the structure of the product determines the class and subclass of an invention drawn to a process of making. The class(s) and subclass(es) must be searched in order to determine the novelty of the process. This is also true for  $E^1$  and  $E^2$ , which are defined in claim 1 as radical suitable for preparing  $R^1$  and  $R^2$ . Substituents  $R^1$ ,  $R^2$ ,  $E^1$  and  $E^2$  are not defined in the specification so as to ascertain what compounds applicant is making. Therefore, there is no adequate support for claims 1-4 in the specification.

Applicant must show possession of the invention by describing it with all the claimed limitations. *Lookwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed Cir. 1997).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-4, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1626

It is not possible to determine the metes and bounds of claims 1-4 for reasons set forth above under 35 USC 112, first paragraph. Therefore, the claims are indefinite.

Claims 1-4, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. The claims are omnibus type claims. For example, the phraseology "under the condensing conditions as are analogously used for carboxylic acids according to the Mitsunobu reaction" on lines 32-33, page 38, claim 3, is indefinite. The claims must stand alone to define the inventions, and incorporation into the claims by express reference to an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. 1993.

Claims 1-4, are written in functional language and therefore, broader than the enabling disclosure. For example, claim 1, recites "under the reaction conditions" (line 20), "organic radical which is suitable for the preparation of" (lines 29-30, page 37); "derivatizing" (line 10, page 38) "reacting" (line 11, page 38), "in one or more further reaction steps" (line 11, page 38) and "removing" (line 22, page 38). Under US patent practice, a process claim must set forth positive steps. Such are the "how to" perform the process instead of "what" is being done in the instant claims. The claims must recite how to perform the above steps. Also, structures of  $R^1$ ,  $R^2$ ,  $E^1$  and  $E^2$  must be disclosed. However, applicants should note that the introduction of new subject matter into the specification would raise the issue of new matter rejection.

Step (b) in claim 1 is confusing and therefore, claims 1-4 are indefinite. It is not clear what applicant is claiming. Appropriate correction is required.

The invention relates to the modifications of  $E^1$  and  $E^2$  to  $R^1$  and  $R^2$ . This is a critical element of the invention but the claims fail to recite how the modifications are performed. The structures of the starting materials and the products are not disclosed. Because the structures of the starting reactants, intermediates and products are not fully disclosed it is not possible to

Art Unit: 1626

perform a complete search of the invention. Applicant is reminded that under US patent practice, to be patentable a claim must be distinct, clear and specific. In patent examination, it is essential for claims to be precise, clear, correct, and unambiguous. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 3718 of this title before the invention thereof by the applicant for patent.

Claims 1-4, are rejected under 35 U.S.C. 102(e) as being anticipated by Baldwin et al., US 5,618,825.

Baldwin et al., disclose a process of making combinatorial libraries of acylsulfonamide compounds on solid support.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, are rejected under 35 U.S.C. 103(a) as being unpatentable over Ort et al., US 5,186,736, in view of Hermkens et al., Tetrahedron, Vol. 52, No. 13, pages 4527-4554, 1996.

Art Unit: 1626

Applicants claim a process for making sulfonamide derivatives having formula I, on solid support, comprising conversion of E1-E2 to R1-R2, wherein R1-R2 and E1-E2 are organic radicals.

Determination of the scope and content of the prior art (MPEP §2141.01)

Ort et al., teach a process of making sulfonamide compounds having formula I, comprising modification of the organic substituents. See column 1 to 16 and examples 1-16.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Ort et al., is that the instant process is performed on a solid support while the process by Ort et al., is performed in solution.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, Hermkens et al., teaches the advantages of carrying out reactions on solid supports on pages 4527-4528. Hermkens et al., also teach a wide variety of reactions that are carried out on solid supports, including various Mitsunobu reactions; various resins are taught that read on the instantly claimed process and several linkers are taught that read on the instant invention. See pages 4530-4550. In addition, Hermkens et al., teach the advantage of solid phase reactions, such as the ability to separate the solid-phase reactants from the solution (Page 4551). Therefore, the instant invention is prima facie obvious from the teachings of Ort et al., and Hermkens et al. It would have been suggested to one of ordinary skill in the art to perform the process of Ort et al., on solid support at the time the invention was made. The motivation is from the teaching of Hermkens et al., on the advantages of solid phase reactions.

This is a CON of applicant's earlier Application No. 10/263,404. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier

Art Unit: 1626

application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

#### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (571) 273-8300.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Application/Control Number: 10/799,256

Page 8

Art Unit: 1626

  
TAOFIQ SOLOLA  
PRIMARY EXAMINER  
Art Unit 1626  
1626

May 12, 2005